



DT06 Rec'd PCT/PTO 22 OCT 2002

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: P. York et al.	)	Atty Docket No.: 0113.00
	)	
	)	Examiner: Unassigned
	)	
Application No. 10/070,093	)	Group Art Unit: Unknown
	)	
Filed: February 27, 2002	)	October 3, 2002
	)	
Title: CONFORMATION METHODS	)	
AND THEIR PRODUCTS	)	

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on 11 OCT 02

Signed: Minno Cotten

INFORMATION DISCLOSURE STATEMENT

UNDER 37 CFR §1.56, §1.97 and §1.98

Commissioner for Patents  
Washington, DC 20231

Dear Sir:

The references listed in the attached Form PTO/SB/08A,B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

Copies of the references are enclosed, as required under 37 CFR §§1.98.

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed:



within three months of the filing date of a national application; within three months of the date of entry of the national stage as set forth in section 1.491 in an international

Attorney Docket No. 0113.00

applicatio before the mailing date of a first Office action on the merits (whichever event occurs last);

- ☐ more than three months from the filing date of an application and after the mailing date of a first Office action on the merits, but before the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311 (whichever occurs first), and is accompanied by:

- ☐ the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under §1.97(c) (\$180.00); or
- ☐ one of the following statements as specified in 37 CFR 1.97(e) that:
- ☐ each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in section 1.56(c) more than three months prior to the filing of the information disclosure statement; or

- ☐ after the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311, but on or before the payment of the issue fee, and is accompanied by each of:

- ☐ the following petition:  
Applicant hereby requests consideration of the accompanying information disclosure statement;
- ☐ the petition fee set forth in 37 CFR 1.17(i) (\$130.00); and
- ☐ one of the following statements as specified in 37 CFR 1.97(e) that:
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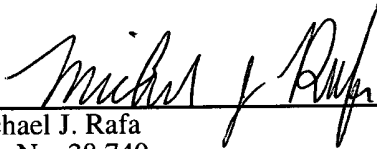
- ☐ Each item of information contained within this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement. Accordingly, this Information Disclosure Statement does not constitute a failure on the part of the Applicant to engage in reasonable efforts to conclude prosecution of the application as set forth in 37 CFR 1.704 "Reduction of period of adjustment of patent term."
- ☐ Attached is Check No. \_ in the amount of \$0.
- ☐ Please charge the amount of \$\_\_\_ to Deposit Account 500348
- ☒ If it is determined that any additional fees are due, the Commissioner is hereby authorized to charge such fees to Deposit Account 50-0348.

Respectfully submitted,

INHALE THERAPEUTIC SYSTEMS, INC.

Dated: 10/7/02

By:

  
Michael J. Rafa  
Reg. No. 38,740

San Carlos, CA 94070  
(650) 631-3100



PTO/SB/08A (10-01)

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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/070.093
				Filing Date	02/27/2002
				First Named Inventor	P. York et al.
				Art Unit	
				Examiner Name	Unassigned
				Attorney Docket Number	0113.00
Sheet	1	of	6		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code 2 (if known)			
	AA	US- 4.328.107	05/04/1982	Wright	
	AB	US- 4.361.285	11/30/1982	Koppehele et al.	
	AC	US- 4.582.731	04/15/1986	Smith	
	AD	US- 4.702.799	10/27/1987	Tuot	
	AE	US- 4.737.384	04/12/1988	Murthy et al.	
	AF	US- 4.919.853	04/24/1990	Alvarez et al.	
	AG	US- 4.923.720	05/08/1990	Lee et al.	
	AH	US- 4.970.093	11/13/1990	Sievers et al.	
	AI	US- 4.977.785	12/18/1990	Willoughby et al.	
	AJ	US- 5.009.367	04/23/1991	Nielsen	
	AK	US- 5.043.280	08/27/1991	Fischer et al.	
	AL	US- 5.106.659	04/21/1992	Hastings et al.	
	AM	US- 5.221.731	06/22/1993	Weymans et al.	
	AN	US- 5.229.486	07/20/1993	Paul et al.	
	AO	US- 5.437.798	08/01/1995	LaRoche et al.	
	AP	US- 5.548.004	08/20/1996	Mandel et al.	
	AQ	US- 5.554.382	09/10/1996	Castor	
	AR	US- 5.639.441	06/17/1997	Sievers et al.	
	AS	US- 5.707.634	01/13/1998	Schmitt	
	AT	US- 5.708.039	01/13/1998	Daly et al.	

FOREIGN PATENT DOCUMENTS							
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		Country Code3	-Number4 -Kind Code5 (if known)				
	AX	DE	4041563	06/25/1992	Schwarz Pharma AG		
	AY	DE	1078283	03/24/1960	F. Aktiengesellschaft		
	AZ	EP	0322687	05/05/1993	W. Fischer		
	BA	EP	0542314	05/19/1993	P. Debenedetti		
	BB	JP	1-176437	07/12/1989	T. Tauchi		
	BC	JP	5-57166	03/09/1993	K. Kitagawa		
	BD	WO	90/11139	10/04/1990	K. Nielsen		
	BE	WO	90/03782	04/19/1990	W. Schmitt		
	CP	GB	2322326	08/26/1998	Bradford Particle		
	CQ	WO	95/21688	08/17/1995	W. Eckhard et al.		

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	of	6		

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		Number - Kind Code <sup>2</sup> (if known)			
	AU	US-5.716.558	02/10/1998	Nielsen et al.	
	AV	US-5.981.474	11/09/1999	Manning et al.	
	AW	US-6.063.910	05/16/2000	Debenedetti et al.	
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		Country Code <sup>3</sup>	Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)			
	CR	WO	95/01221	01/12/1995	Univ. Bradford	
	CS	WO	96/00610	01/11/1996	Univ. Bradford	

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		Application Number	10/070.093		
		Filing Date	02/27/2002		
		First Named Inventor	P. York et al.		
		Group Art Unit			
		Examiner Name	Unassigned		
Sheet	3	of	6	Attorney Docket Number	0113.00

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
BF		DEBENEDETTI ET AL., "Application of Supercritical Fluids for the Production of Sustained Delivery Devices," J. Cont. Rel. No. 24, p. 27-44 (1993).	
BG		DIXON ET AL., "Polymeric Materials Formed by Precipitation with a Compressed Fluid Antisolvent," AIChE J., Vol. 39 (No. 1), p. 127-139 (1993).	
BH		TOM ET AL., "Applications of Supercritical Fluids in the Controlled Release of Drugs," ACS Symposium Series, Supercritical Fluid Engineering Science Fundamentals and Applications, Chpt. 19, p. 238-257 (1993).	
BI		LARSON ET AL., "Evaluation of Supercritical Fluid Extraction in the Pharmaceutical Industry," Biotech. Progress, Vol. 2 (No. 2), p. 73-82 (1986).	
BJ		Ullmans Encyclopedia of Industrial Chemistry, Vol. B2, Fifth Ed., title page, copyright page, and p. 7-21 and 7-22 (1988).	
BK		TOM ET AL., "Particle Formation with Supercritical Fluids - A Review," J. Aerosol Sci., 1st Ed. Vol. 22 (No. 5), p. 555-584 (1981).	
BL		DEBENEDETTI ET AL., "Rapid Expansion of Supercritical Solutions (RESS): Fundamentals and Applications," Fluid Phase Equilibria, Vol. 82, p. 311-321 (1993).	
BM		GALLAGHER ET AL., "Gas AntiSolvent Recrystallization: New Process to Recrystallize Compounds Insoluble in Supercritical Fluids," ACS Symp. Ser No. 406, p. 334-354 (1989).	
BN		LAHIERE ET AL., "Mass-Transfer Efficiencies of Column Contactors in Supercritical Extraction Service," Ind. Eng. Chem. Res. No. 26, p. 2086-2092 (1987).	
BO		STAHL ET AL., "Dense Gas Extraction on a Laboratory Scale: A Survey of Some Recent Results," Fluid Phase Equilibria, No. 10, p. 269-278 (1983).	
BP		DILL ET AL., "Denatured States of Proteins," Annu. Rev. Biochem, No. 60, p. 795-825 (1991).	

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<b>OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BQ	O'CALLAGHAN ET AL., "Novel Method for Detection of (B)-Lactamases by Using a Chromogenic Cephalosporin Substrate," Antimicrobial Agents and Chemotherapy, Vol. 1 (No. 4), p. 283-288 (1972).	
	BR	JUNG ET AL., "Particle Design Using Supercritical Fluids: Literature and Patent Survey," J. of Supercritical Fluids, Vol. 20, p. 179-219 (2001).	
	BS	BLEICH ET AL., "Aerosol Solvent Extraction System - A New Microparticle Production Technique," International J. of Pharmaceutics, Vol. 97, p. 111-117 (1993).	
	BT	CHANG ET AL., "Separation of B-Carotene Mixtures Precipitated from Liquid Solvents with High-Pressure CO <sub>2</sub> ," Biotechnol. Prog., No. 7, p. 275-278 (1991).	
	BU	GALLAGHER ET AL., "Gas Anti-Solvent Recrystallization of RDX: Formation of Ultra-fine Particles of a Difficult-to-Comminute Explosive," The J. of Supercritical Fluids, No. 5, p. 130-142 (1992).	
	BV	MATSON ET AL., "Production of Powders and Films by the Rapid Expansion of Supercritical Solutions," J. of Materials Science, No. 22, p. 1919-1928 (1987).	
	BW	MOHAMED ET AL., "Solids Formation After the Expansion of Supercritical Mixtures," Supercritical Fluid Science and Technology, Chapter 23, American Chemical Society, p. 355-378 (1989).	
	BX	BARJ ET AL., "Submicronic MgAl <sub>2</sub> O <sub>4</sub> Powder Synthesis in Supercritical Ethanol," J. of Materials Sci., No. 27, p. 2187-2192 (1992).	
	BY	CHHOR ET AL., "Synthesis of Submicron TiO <sub>2</sub> Powders in Vapor, Liquid and Supercritical Phases, a Comparative Study," Materials Chemistry and Physics, Vol. 32, p. 249-254 (1992).	
	BZ	FRANCIS, "Ternary Systems of Liquid Carbon Dioxide," J. of Physical Chemistry, Vol. 58, p. 1099-1114 (1954).	
	CA	YEO ET AL., "Formation of Microparticulate Protein Powders Using a Supercritical Fluid Antisolvent," Biotechnology and Bioengineering, Vol. 41, p. 341-346 (1993).	

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Sheet	5	of	6	Attorney Docket Number	0113.00

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CB	RANDOLPH ET AL., "Sub-Micrometer-Sized Biodegradable Particles of Poly (L-Lactic Acid) via the Gas Antisolvent Spray Precipitation Process," Biotechnol. Prog., Vol. 9, No. 4, p. 429-435 (1993).	
	CC	DEBENEDETTI ET AL., "Supercritical Fluids : A New Medium for the Formation of Particles of Biomedical Interest," Proceed. Intern. Symp. Control Rel. Bioact. Mater., 20, p. 141-142 (1993).	
	CD	DONSI ET AL., "Micronization by Means of Supercritical Fluids: Possibility of Application to Pharmaceutical Field," Pharm. ACTA HELV. 66, Nr. 5-6, p. 170-173 (1991).	
	CE	CYGNAROWICZ ET AL., "Design and Control of a Process to Extract B-Carotene with Supercritical Carbon Dioxide," Biotechnol. Prog. Vol. 6, p. 82-91 (1990).	
	CF	CHEN ET AL., "Supercritical Antisolvent Fractionation of Polyethylene Simulated with Multistage Algorithm and SAFTEquation of State: Staging Leads to High Selectivity Enhancements for Light Fractions," Ind. Eng. Chem. Res., Vol. 33, p. 306-310 (1994).	
	CG	LOTH ET AL., "Properites and Dissolution of Drugs Micronized by Crystallization from Supercritical Gases," International J. of Pharmaceuticals, Vol. 32, p. 265-267 (1986).	
	CH	BODMEIER ET AL., "Polymeric Microspheres Prepared by Spraying Into Compressed Carbon Dioxide," Pharmaceutical Research, Vol. 12, No. 8, p. 1211-1217 (1995).	
	CI	TOM ET AL., "Formation of Bioerodible Polymeric Microspheres and Microparticles by Rapid Expansion of Supercritical Solutions," Biotechnol. Prog., Vol. 7, p. 403-411 (1991).	
	CJ	SANCHEZ ET AL., "Development of Biodegradable Microspheres and Nanospheres for the Controlled Release of Cyclosporin A," International J. of Pharmaceutics, Vol. 99, p. 263-273 (1993).	
	CK	JULIENNE ET AL., "Preparation of Poly (D, L-Lactide/Glycolide) Nanoparticles of Controlled Particle Size Distribution: Application of Experimental Designs," Drug Development and Industrial Pharmacy, Vol. 18, No. 10, p. 1063-1077 (1992).	
	CL	PHILLIPS ET AL., "Rapid Expansion from Supercritical Solutions: Application to Pharmaceutical Processes," International J. of Pharmaceutics, Vol. 94, p. 1-10 (1993).	

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		CHANG ET AL., "Precipitation of Microsize Organic Particles from Supercritical CM Fluids," AIChE Journal, Vol. 35, No. 11, p. 1876-1882 (November 1989).	
		MATSON ET AL., "Rapid Expansion of Supercritical Fluid Solutions: Solute Formation of Powders, Thin Films and Fibers." Ind. Eng. Chem Res., Vol. 26, p. 2298-2306 (1987).	
		STENGERS ET AL., "Carbon Dioxide at its Critical State," Chemical & CO Engineering News, June 10, 1968.	

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